PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference WO/169	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/11689	International filing date *(day/month/year)* 22.10.2003	Priority date *(day/month/year)* 25.10.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/192		
Applicant DOMPE S.P.A. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28.04.2004	03.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Beyss, E Telephone No. +49 30 25901-344

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/11689

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-11 as originally filed

Claims, Numbers

1-3 as originally filed

Drawings, Sheets

1-3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-3
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-3
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-3
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-B-63425301
D2: US-A-5895789

1. Novelty

D1 describes pharmaceutical formulations containing d,l- or l-lysine salt of R,S- or S-ibuprofen suitable for parenteral administration wherein the pH is adjusted to 7.2 to 7.6 (claim 1; column 4, line 62).

D2 describes pharmaceutical formulations containing 2-arylpropionic acid like ibuprofen suitable for parenteral administration wherein the pH is adjusted to 7.0 to 7.5 (claim 1).

Present application discloses pharmaceutical compositions containing 2-arylpropionic acids suitable for parenteral administration wherein the pH is in the range between 8 to 9. The subject-matter of claims 1-3 is therefore new (Article 33(2) PCT).

2. Inventive Step

D1 is considered to represent the most relevant state of the art. The problem to be solved by the present invention may be regarded as the provision of pharmaceutical compositions suitable for parenteral administration which contain salts of 2-arylpropionic acids and which generate no pain upon injection (page 1, line 1-4).

The solution to this problem proposed in claims 1-3 of the present application is considered as involving an inventive step (Article 33(3) PCT) since neither D1 nor D2 gives a hint nor suggestion that a formulation having a pH of 8 to 9 are less painful upon injection.

The results of the experiments as outlined in tables 4-8 show that formulations according to claims 1-3 are unexpectedly less painful upon administration than compositions having a lower or higher pH.

3. Industrial Applicability

Claims 1-3 meet the requirements of Article 33(4) PCT.